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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,304	12/01/2003	Lars Lindberg	P03,0559	2896

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SCHIFF HARDIN & WAITE
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EXAMINER

ALI, SHUMAYA B

ART UNIT	PAPER NUMBER
3771	

MAIL DATE	DELIVERY MODE
09/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/725,304	Applicant(s) LINDBERG ET AL.	
	Examiner Shumaya B. Ali	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/17/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement filed 1/8/07 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because IDS does not provide a list of references to be considered. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

Applicant declaration is defective because it recites "material to **the** patentability."

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the **“the cuff having a membrane” (current drawing depicts cuff being the membrane instead of a separate structure) and “dosing unit in fluid communication with said flow path” (current drawing depicts dosing tube 22 is in communication with a tracheal tube 4, however not with pumping device 12, tubes 8 and 10, making up the flow path as claimed)** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: specification on page 7, line 23 states, "the membrane 6A in the cuff 6," however figure 1 does not depict that, instead shows cuff is the membrane. Examiner also sees the cuff being the membrane. Applicant is requested to clarify whether the cuff and the membrane are same or two separate elements.

Claim 6 is objected to because of the following informalities: specification does not provide support for all first and second chamber tubes "in fluid communication with said pumping device" as cited in lines 7 and 9. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 9, "a specific substance" is indefinite. It is not clear whether "specific" is considered one substance and/or selective permeability of many substances? The number of substances being limited by "specific" cannot be determined, which renders claim indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Kruse et al. US 5,957,839.

As to claim 1, Kruse discloses a medical device (see fig.1) comprising: a cuff (14) adapted for positioning in the trachea of a subject with a patient tube; a first tube (20) having a first end in fluid communication with an interior of the cuff (see fig.1) and having an opposite, second end (connecting 56); a second tube (22) having a first end in fluid communication with the interior of the cuff (see fig.1) and having an opposite, second end (connecting 56); a pumping device (52) connected to the respective second ends of the first and second tubes for circulating a fluid through the interior of the cuff (col.8, lines 34 and 35); and said cuff having a membrane (col.6, lines 30-33) that is permeable to a specific substance (gas), said membrane being disposed to allow transfer of said specific substance between the interior of the cuff and an exterior of the cuff (col.6, lines 30-33).

As to claim 2, Kruse discloses a medical device as claimed in claim 1 wherein said pump, said first and second tubes, and said cuff form a flow path (fig.1 depicts two tubes are connected to the pump, therefore, a flow path is inherently established between said pump and tubes) for said fluid, and wherein said medical device comprises an analysis unit (72) in fluid

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communication with said flow path for analyzing said fluid with regard to content in said fluid of said specific substance (col.10, lines 63-68, and col.11, lines 1-24).

As to claim 3, Kruse discloses a medical device as claimed in claim 2 wherein said analysis unit includes a calculation unit (76) that quantitatively determines an amount of said specific substance in said fluid relative to a predetermined normal amount (col.10, lines 63-68, and col.11, lines 1-24).

As to claim 4, Kruse discloses a medical device as claimed in claim 1 wherein said pumping device, said first and second tubes, and said cuff form a flow path (fig.1 depicts two tubes are connected to the pump, therefore, a flow path is inherently established between said pump and tubes) for said fluid, and wherein said medical device comprises a dosing unit (46) in fluid communication with said flow path for administering a dose of a medicament into said fluid (col.7, lines 43-59).

As to claim 5, Kruse discloses a medical device as claimed in claim 4 wherein said dosing unit comprises at least one reservoir (a syringe inherently has a reservoir/space where gas will be held inside 46) for at least one additive substance for inclusion in said medicament.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kruse et al. and in view of Schultze US 4,141,364.

As to claim 6, Kruse lacks wherein said cuff comprises at least one partition wall that partition the interior of said cuff into multiple chambers. However, Schultze teaches endotracheal tube cuff with multiple chambers (see figs. 7 and 8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kruse in order to provide multiple chambers because it is known in the art as taught by Schultze. Kruse further lacks each chamber having a first chamber tube with a first chamber tube end in fluid communication therewith and a second chamber tube with a first chamber tube end in fluid communication therewith, and wherein said first chamber tube has a second chamber tube end and said second chamber tube has a second chamber tube end in fluid communication with said pumping device for circulation of respectively separate fluids through the multiple chambers. However, since Kruse teaches at least two tubes are in communication with the cuff at a different location within the cuff, and one end of each tube is connected to a pumping device, it would have been obvious to have each tubes of Kruse connected to separate chambers of Schultze. It would have been further obvious to have multiple tubes (i.e. first and second chamber tubes of first and second chamber as claimed) connecting to the cuff because it has been held that mere duplicate of tubes only requires routine skills in the art. Furthermore, it would have been obvious to one of ordinary skill in the art to increase the number of tubes to expedite fluid circulation within the medical device.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kruse et al. and in view of Hanson et al. US 5,985,307 and in further in view of Walther et al. US 6,660,833 B1.

As to claim 7, Kruse lacks wherein said membrane is permeable to at least one protein, as said specific substance, selected from the group of proteins consisting of SP-A, SP-B, SP-C and SP-D that are present in surfactant. However, Hansen teaches a balloon cuff membrane device that can be used to deliver therapeutic agent in the respiratory tree (see col.2, lines 44 and 45) to treat a variety of disease syndromes (see col.18, lines 55 and 56). Although Hansen's device is permeable to protein (i.e. antibody, see col.26, line 55), Hansen however is silent on the claimed protein. However, Walther teaches respiratory distress syndrome therapy using peptide analogs of human SP-B that mimics human surfactant protein B (see abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kruse in order to provide a membrane that allowed protein to pass through in the respiratory tree for the purposes of treating respiratory disease syndrome as taught by Hansen and further modify the membrane to be selective to SP-A for the purposes of treating respiratory distress syndrome as taught by Walther.

Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sahatjian (5,533,516), Zapol (5,536,241), Ise (6,737,243), Boussignac (6,761,172), Gobel (6,802,317), Ranzinger (6,923,176), and Kimura (2007/0137621) pertain to tube with cuff member.

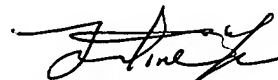
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Shumaya B. Ali
Examiner
Art Unit 3771


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8/31/07